

**"510(k) SUMMARY"**

8.1 Trade/Proprietary Name: Disetronic Penfine® Injection Pen Needle

8.2 Common/Usual Name: Injection Pen Needle

8.3 Classification Name: ~~Hypodermic Single Lumen Needle~~

8.4 Comparison to Currently Marketed Devices

The 6 mm Disetronic Penfine® Injection Pen Needles are substantially equivalent to the 8, 10 and 12 mm Disetronic Penfine® Injection Pen Needles (K982399).

8.5 Device Description

The 6 mm Disetronic Penfine® Injection Pen Needles are the same sterile, non-pyrogenic, single use needles designed to be used with commercially available Injection Pens as the 8, 10 and 12 mm Disetronic Penfine® Injection Pen Needles. The only difference is in the length of the cannula.

8.6 Indications for Use

The Disetronic Penfine® Injection Pen Needles are intended for the hypodermic injection of fluids into the body when attached to an injector pen.

8.7 Technological Characteristics

The technological characteristics are the same as the predicate devices.

8.8 Performance Data

Performance data has been generated in compliance with existing international standards and protocols and found equivalent to the predicate devices.

8.9 Conclusion

Based on the design equivalency and the functional and safety testing, Disetronic Medical Systems has determined that the Penfine® Injection Pen Needles are substantially equivalent to the devices currently marketed in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 29 1999

Mr. David E. Chadwick, Ph.D.  
Director, Regulatory Affairs  
Disetronic Medical Systems, Inc.  
5151 Program Avenue  
St. Paul, Minnesota 55112-1014

Re: K994197

Trade Name: Disetronic Penfine® Injection Pen Needle  
Regulatory Class: II  
Product Code: FMI  
Dated: December 7, 1999  
Received: December 13, 1999

Dear Mr. Chadwick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

*Timothy A. Ulatowski*

Timothy A. Ulatowski *TU*  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) File Number: 1K 99 419 7

Device Name: Disetronic Penfine® Injection Pen Needle

Indications For Use: The Disetronic Penfine® Injection Pen Needles are intended for the hypodermic injection of fluids into the body when attached to an injector pen.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.19)

OR

Over-The-Counter Use \_\_\_\_\_

Michael W. Shyns  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
Number 1K 99 419 7